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FACET INJECTION STUDY

**Facet-joint injections for people with persistent non-specific low back pain (FIS)
Consensus Conference**

27th June 2014

Scarman Conference Centre, University of Warwick

Report

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On Behalf of the FIS Team and the FIS Consensus Group

February 2015

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Summary

A consensus conference involving health professionals active in the management of facet joint pain along with lay representatives to discuss and agree five design considerations for a feasibility study in advance of a clinical trial of facet joint injections. The design considerations concerned: diagnosis, the process of facet joint injection, best usual care, size of signal (minimal important change/difference) and sub-groups for analysis. The consensus conference was provided with systematic evidence reviews on each of these design considerations, opportunity for discussion in small groups and a series of nominal group technique rankings. Of the 50 attendees only 3 dissociated themselves from the final consensus outcome. Post conference clarifications were undertaken by email. The design of the feasibility study protocol was altered to incorporate consensus findings and is available at:

http://www.nets.nihr.ac.uk/_data/assets/pdf_file/0019/130654/PRO-11-31-01.pdf

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Background

The Facet Injection study (FIS) is one of two studies commissioned in 2014 (NIHR, HTA) to assess the clinical- and cost-effectiveness of facet-joint injections in selected patients with non-specific low back pain. The other project is comparing facet joint injections with local anaesthetic and steroid to a sham procedure in people with positive diagnostic test for facet joint disease. (See <http://www.controlled-trials.com/ISRCTN12191542/12191542>). In our study we will explore the feasibility of running a randomised controlled trial to test the hypothesis that, for people with suspected facet joint pain contributing to persistent low back pain, adding the option of facet joint injections, with local anaesthetic and corticosteroids, to best usual non-invasive care available from the NHS is clinically and cost-effective.

To ensure that the FIS protocol was robust and informed by current evidence and expert opinion, was acceptable to the academic community and practicing clinicians and reflected NHS practice a four stage process was adopted. First, the FIS team identified key design considerations that are of vital importance for the production of robust and acceptable evidence on an implementable facet joint injection programme. Second, an evidence review of each design consideration was conducted using systematic methodology. Third, an evidence document was prepared that contextualised the pragmatic FIS, outlined the methodological challenges of designing a credible pragmatic trial and presented the outputs from the evidence reviews. Fourth, using the evidence document as a delegate pack the FIS design considerations were considered by a consensus conference of clinicians, experts, academics and patients.

This report describes the FIS (Facet injection Study) design considerations and their implications for the study, the consensus conference process, its results and discuss how this has helped to shape the study protocol. The methods and results sections are divided into pre conference, conference and post conference phases.

The Facet Injection study team identified five design considerations:

1. Diagnosis
2. Process of facet joint injection
3. Management/rehabilitation of those with of those with facet joint pain (Best Usual care)
4. Size of signal (Minimal important change/difference)
5. Sub-groups for analysis

Figure 1 provides an overview of the whole process

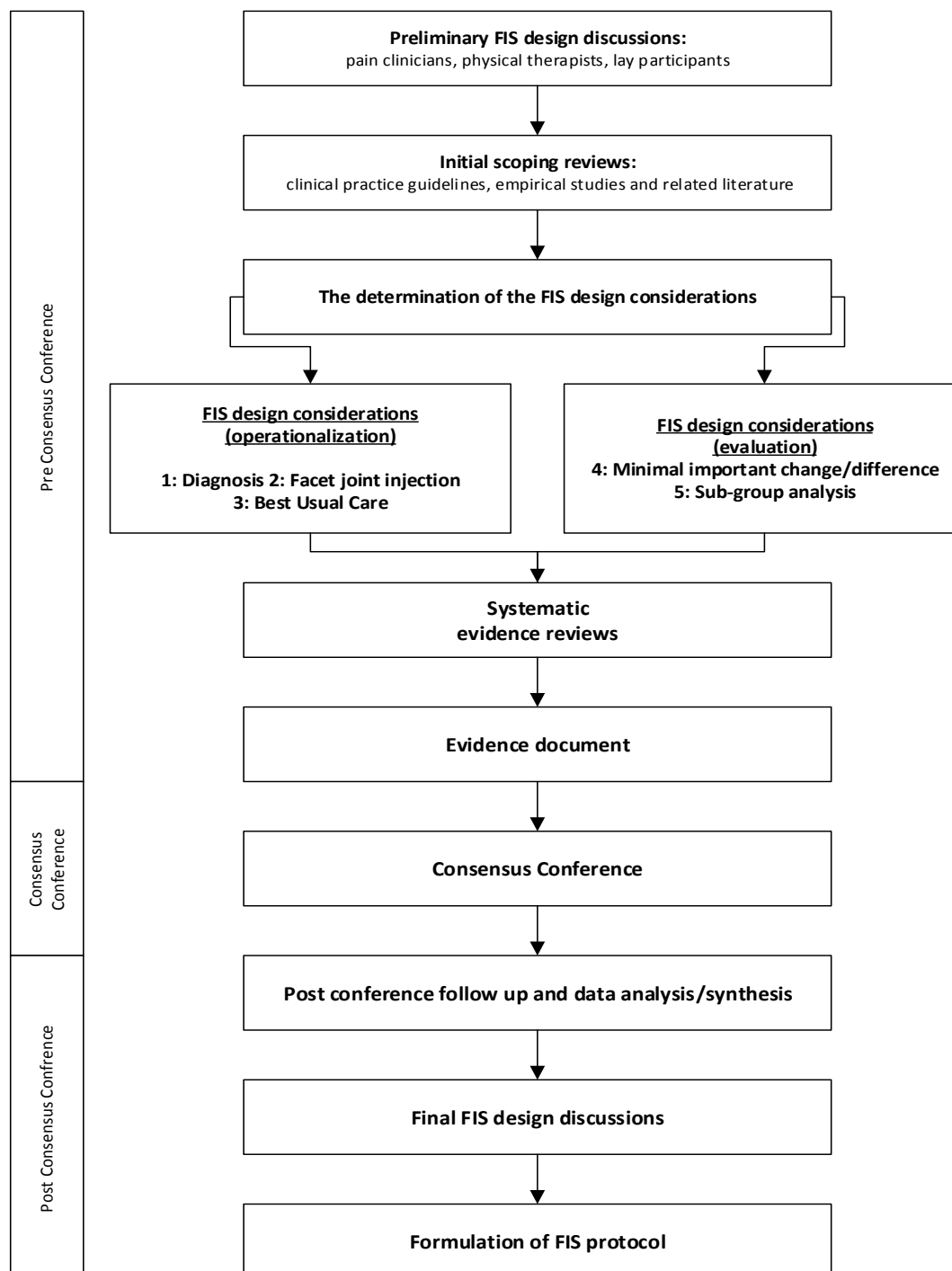
Methods

Pre conference:

The research team undertook scoping reviews of clinical practice guidelines, empirical studies and related literature and discussed project design.. Discussions included pain clinicians, physical therapists and lay representatives. From this process key design considerations for this study were identified.

These design considerations were taken forward for discussion at a consensus conference. To inform consensus development an evidence document was produced based on systematic reviews of current literature.

Figure 1. Facet Injection Study Protocol Development Process



The conference was organised to cover a whole day (between 9am and 4.30) at a conference centre at the University of Warwick, UK. Invitations to the conference were distributed through relevant professional organisations and lay groups. There was no charge for attendance and out-of-pocket travel expenses were paid.

Evidence documents were sent to all those who registered to attend approximately one week before the conference.

Consensus conference:

The conference included discussion of the design considerations and, to reach consensus, the use of nominal group technique (NGT) as this allows for confidential ranking of options. As noted earlier we had five key design considerations for discussion at the conference. The morning consisted of four sessions. The first was an introduction to remind all participants of the design considerations and evidence and to explain the consensus process. This was followed by three one hour long small group discussions. In each of the three morning sessions the participants were divided into five small groups for discussion (in separate rooms) along with the first round of NGT. The three 'operational' design considerations (diagnosis, injection and best usual care) were discussed by four differently constituted groups. Minimal important change was discussed by two groups and sub-group analysis one. Prior to the day all delegates were randomly assigned to small group discussion stratified by profession (approximately 10-12 per group). This ensured that all delegates were able to participate in three different discussion groups during the morning. Delegates were assigned to a group but would find they were with different people in each of the three groups they attended. The afternoon, plenary, session brought together results from the morning sessions for further discussion and ranking through NGT. All sessions were audio recorded to allow clarification of what happened in the groups during analysis.

The small groups had a trained facilitator, a scribe (Medical Student) and a subject expert from the research team. The expert DID NOT participate in the discussions but was there to aid with technical points. Discussions centred on the particular design consideration often with the suggested 'protocol' as a starting point. In the groups on injection and best usual care, due to the large number of topics to be covered, delegates were asked if each of the suggested techniques was acceptable (i.e. not necessarily what they themselves would do or advise but an acceptable method/technique). Those where there was lack of agreement in the group were discussed. Ranking and re-ranking was used when required to come to a conclusion for the group at the end of the session.

During the lunch break all of the morning sessions were collated and results from the small groups were taken forward to the afternoon plenary session. Each of the topics was presented and discussed. Ranking was used to finalise results where there was no consensus emerged from the small groups.

Post Conference:

All results were carefully checked and verified from both the morning and afternoon sessions. A small number of errors were found and the team contacted relevant groups of delegates via email to clarify and reach a consensus on these items.

The results of the day were used to inform the writing of the protocol for the facet injection study.

Results

Pre Conference:

A full evidence document was produced (78 pages plus) for each delegate and distributed electronically before the day and provided in hardcopy on the day. This included tabulated results of the searches, brief summaries and in several cases suggested 'protocols'. Note: a copy of the evidence document can be requested from the FIS team at FIS@warwick.ac.uk (this document is copyright).

For each design consideration a question was posed in the evidence document for consideration at the consensus conference. These were:

- Diagnosis
 - What is the best choice of clinical assessment to identify patients with suspected facet joint pain?
- Injection technique
 - What is the agreed technique for the injection of facet joints?
- Best usual Care
 - What is the optimal conservative management/rehabilitation for patients with low back pain where facet joints have been identified as a contributing source of symptoms?
- What is the difference in magnitude of response between treatment and control groups that should be considered large enough to establish the scientific or therapeutic importance of the results?
 - What is the minimal between-group difference in change scores necessary for Facet Joint Injection(s) to be considered worthwhile?
 - At 3-months, should we be seeking a mean between-group difference in change scores that is smaller / the same / or larger than that observed for the trials of manual therapy?
 - Informed by the MID-units calculated for the trials of manual therapy (supporting evidence), at 3-months should we be seeking a small (<0.5), medium (0.5-1.0) or large (>1.0) MID-unit as proof of important difference?
 - What magnitude of reduction in pain after the injection constitutes immediate pain relief?
 - What proportion of those we inject should obtain immediate pain relief, based on the agreed definition, for us to conclude we have selected a population likely to benefit from facet joint injections?
- Which variable(s) should be used for a priori sub-group analyses in the main trial?

As noted earlier a 'protocol' for injection technique and best usual care, based on the evidence reviews was presented as a starting point for discussion in the evidence document. We briefly outline these here.

Suggested study protocol for facet joint injection

We describe here, as a starting point for discussion, the protocol for injecting facet joints that we have proposed to the funders.

When they attend for injection the operator will make a brief clinical assessment to satisfy themselves that facet joint injections are appropriate. Consent for the procedure will be obtained and the current pre-injection risk management procedures of the participating study centres will be adhered to. The operator will then inject the facet joint(s). We anticipate injecting up to six facet joints in each individual (L3/L4, L4/L5; L5/S1) bilaterally. However, where, on clinical assessment, there is unilateral pain, or

involvement of only some levels the operator may choose to do unilateral injection, or be selective on levels injected. We anticipate that everyone should receive at least two injections. This pragmatic approach reflects what actually happens in NHS practice. This approach is consistent with that used in trials of other complex interventions for low back pain, e.g. manual therapy or a cognitive behavioural approach, where practitioners choose from a limited range of options based on their clinical assessment of the patient.

Procedure to position the needle:

- We do not anticipate using intravenous sedation.
- Prone position with pillow under abdomen to flatten lumbar lordosis.
- Intravenous access, resuscitation equipment available.
- Skin cleansing with chlorhexidine 0.5% or 2% in alcohol, sterile drapes. (Some clinicians think that 2% chlorhexidine is neurotoxic and like to use 0.5% as skin cleansing before nerve blocks. On the other hand 2% chlorhexidine is recommended by the control-of-infection experts as optimum skin cleansing before intravenous cannulation and may be preferred in some Trusts).
- X-ray imaging (C-arm fluoroscopy) oblique view to visualise joint.
- The dose of radiation used will be adequate to visualise the joint while minimizing X-ray exposure.
- Skin weal at needle entry point: 1% lidocaine via 25G hypodermic needle.
- 22G x 3.5 inch (0.7 x 90 mm) needle with Quincke type point guide to joint cleft.
- Entry to the joint cleft may be indicated by X-ray appearance: observation of the needle tip on the joint line with medial/lateral movement of the X-ray beam to cause parallax shift.
- If entry to the joint has not been achieved after repositioning the needle twice, the needle will be positioned on the joint line without further attempts at capsular puncture.
- Aspiration should be negative for blood or cerebrospinal fluid.
- We do not anticipate using contrast medium because of the restriction of available joint volume and the risk of serious allergic reactions.
- The immediate post injection advice will be in accordance with the current procedures of the participating study centre.

Injection:

- Pre-filled syringes containing bupivacaine 7.5mg and methyl prednisolone 20mg in total volume; 2ml will be used for each joint.
- The full volume, 2ml, will be injected through the spinal needle placed into each joint. Some facet joints may not be sufficiently large to take this volume of injectate meaning in practice that the injections will be intra- and peri-articular. This reflects what we believe to be current practice in the UK.
- Resistance to injection may occur due to abutment of the needle bevel to a surface or due to filling of the intra-articular space:
 - Force should not be used.
 - The needle should first be rotated 90° and a further attempt at injection made.
 - If, after two further 90° rotations resistance to injection persists or if, after successful injection of a part volume resistance develops, gentle pressure should be maintained on the plunger and the needle withdrawn gradually until resistance to injection falls.

After completion of the injection the needle is removed and a sterile dressing applied.

Preliminary outline content and structure of 'Best Usual Care' package (the control intervention)

Initial assessment

Initial assessment of 60 minutes. Assessment includes discussion of expectations, fear avoidance and self-efficacy to assess any perceived challenges and barriers that patients feel may be preventing them from engaging in self-management of chronic pain and to allow subsequent treatment sessions to be tailored to individual need. For the intervention group, the facet joint injections are given in the period between this first assessment and the first follow-up appointment.

Individual sessions

Five further sessions each of 30-minutes incorporating elements of manual therapy, pacing, motor control retraining, therapeutic exercise, soft tissue stretches/release, postural and general advice, goal setting and challenging negative thoughts associated with physical activity and chronic low back pain as appropriate.

Manual therapy (MT) intervention may include:

- Passive accessory intervertebral movements; either central, unilateral applied to either the symptomatic level or the level adjacent depending on the severity and irritability.
- Soft tissue release/trigger point release/muscle energy techniques as indicated in order to facilitate motor control retraining and effectiveness of manual therapy
- Manipulation treatment as indicated.
- Active exercise to increase mobility, improved motor control and core stability, improve overall strength and stretch any tight muscle groups.
- Mobility techniques such as flexion in lying, pelvic tilt, side glides in standing and gym ball exercises.
- Motor control retraining exercises (depending on individual assessments). This may include all muscles involved in core stabilising of the spine and also reducing activity in more superficial muscles that have been shown to become over active in the presence of LBP. Treatment focuses on retraining the 'co-activation' pattern of stabilising muscles such as transversus abdominus and lumbar multifidus (LM). This includes retraining of lumbar multifidus as it is innervated by the medial branch and becomes inhibited ipsilateral to the pain in chronic back pain conditions. There is also evidence that specific retraining of 'core muscles' can improve pain and disability in some back pain patients.
- Passive stretches. Muscle groups identified during assessment as tight or overactive may be stretched within the therapy sessions in order to allow for improved spinal mobility and facilitate motor control retraining. Stretches taught as part of the home exercise regime.

Home exercises and advice may include:

- Bespoke exercise programme to complement face to face sessions. Prescription to include frequency, dose, repetitions and progressions.
- Advice on positions of ease, strategies to use in event of a 'flare-up', and strategies to reduce increasing pain e.g. use of pelvic tilt prior to standing after prolonged sitting.

Cognitive approaches may include:

- Pacing including discussion of what is meant by pacing, relevance of pacing and methods to incorporate pacing into daily activities such as pacing by time, pacing by numbers or pacing by grading activities.
- Goal setting, including discussion of setting mutually agreed goals related to functional activities as well general daily goals and long term goals. Goals agreed between the physiotherapist and

patient participant. In line with a CB approach, goals may be based on SMART principles; Specific, Measurable, Achievable, Realistic and have a Time frame (a date for competition).

- Challenging negative automatic thoughts (cognitive restructuring) including, working with patients to identify particular negative thoughts they may have in relation to physical activity and fear avoidance, and helping patients challenge their thoughts and adapt positive coping strategies.
- Homework tasks between each session tailored to each individual and what is discussed during the session. For example, using pacing on a particular activity identified by the patient, keeping a diary of negative automatic thoughts that may trigger anxieties about movement or exercise and pain.

Conference:

On the day of the conference 50 attended of the 57 who had confirmed attendance, Table 1. gives an overview of attendees.

Table 1. Overview of those who attended the consensus conference

| Role | |
|---|----|
| Pain consultants and physicians | 19 |
| Anaesthetists | 6 |
| Physiotherapist or Physical specialists | 12 |
| Academics | 2 |
| Psychologists | 3 |
| Radiographers | 2 |
| Lay representatives | 6 |

Below we present the results from the morning small group sessions (using nominal group technique) for each of the design considerations. The results from these were taken forward to the afternoon plenary session.

Diagnosis

Table 2. gives an overview of all of the results from the four morning group sessions which were taken forward to the plenary session in the afternoon for discussion and consensus. Key components of a diagnostic assessment were discussed including increased pain on extension or rotation, rising from flexion and extension/lateral flexion; in addition, no radicular symptoms, no SI joint pain, and in a pain provocation test flexion less painful than extension. Consensus was not reached on the day, see post-conference results below.

The process of facet joint injection

Table 3. gives an overview of the results from the four morning sessions and the plenary session in the afternoon. Delegates had 14 items to consider in this session covering all aspects of the process. Many of these were deemed to be 'acceptable' by the groups for use in practice and required no further discussion. Alternatives were suggested where there was disagreement and results taken to plenary session. Table 4. shows that much of the protocol for injection technique was agreed in this session. However, verifying the results post-conference several errors in rankings and votes were found these were resolved with email votes sent to delegates post-conference. The outcome of this is reported below.

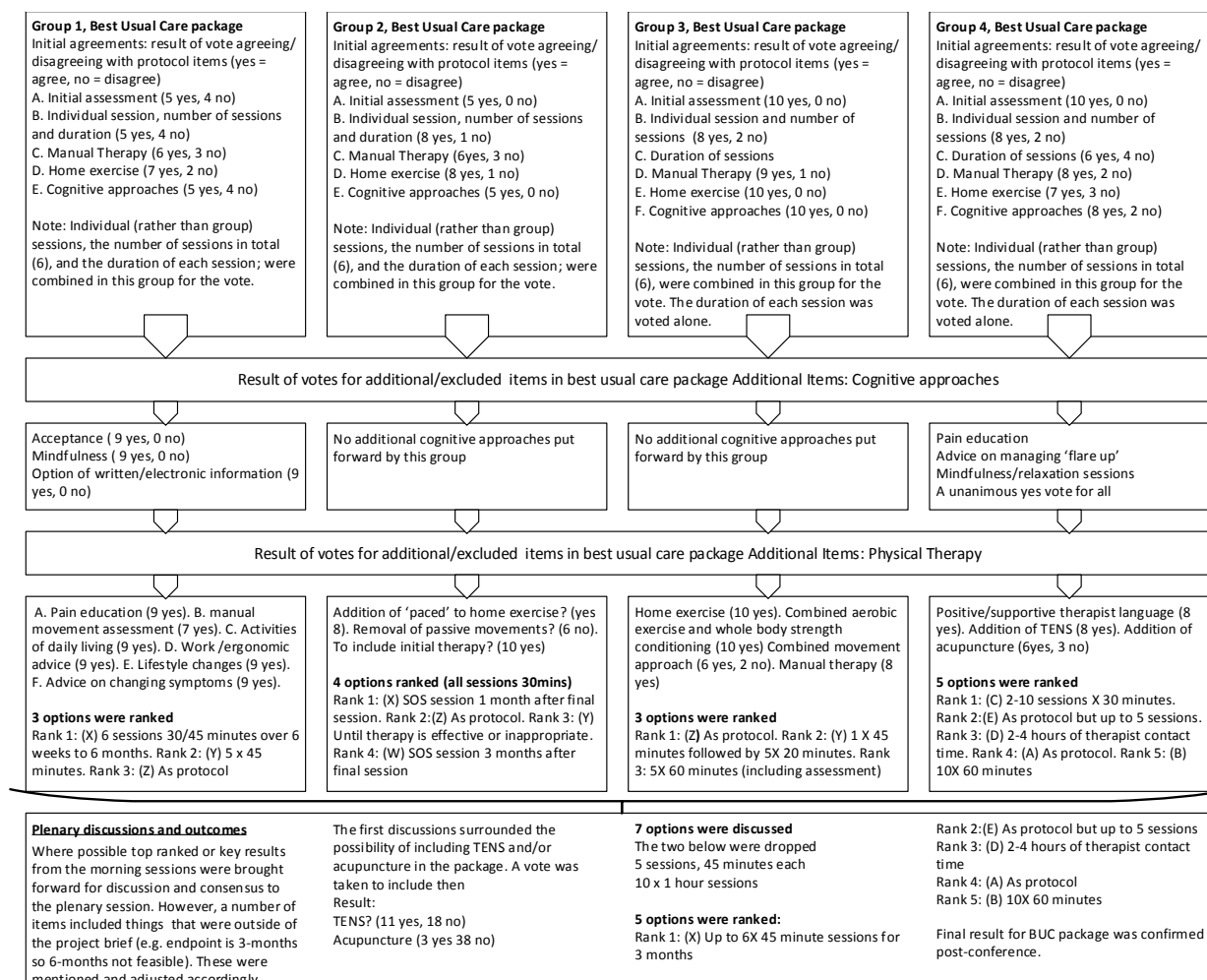
Table 2. Group and Plenary Results from Facet injection Study Consensus Conference looking at: What is the best choice of clinical assessment to identify patients with suspected facet joint pain?

| | | | |
|---|---|---|---|
| <p>Diagnosis group 1 Group generated list of 7 options:</p> <ul style="list-style-type: none"> a) Extension and Ipsilateral side bending (standing) b) Extension and Ipsilateral rotation (prone) c) Psychological distress d) Para-Median tenderness e) MRI Lumbar spine W. Hypertrophic facet joints or fluid f) Personality inventory g) Focal low back pain <p>The first round of ranking excluded: e & f</p> <p>The top 5 were then ranked again:</p> <p>Rank 1: G: Focal low back pain Rank 2: A: Extension / Ipsilateral side bending (standing) Rank 3: D. Para-Median tenderness Rank 4: C. Psychological distress Rank 5: B. Extension and Ipsilateral rotation (prone)</p> | <p>Diagnosis group 2 Group did not vote but agreed on a diagnostic pathway (outlined below).</p> <p>HISTORY (in. absence of Red Flags)</p> <ul style="list-style-type: none"> • Gradual onset (usual) • Lumbar sacral • Localised (no pain below knee) • back pain predominant feature • No neurological symptoms • Relieved at rest • Mechanical presentation • Worse on weight bearing • Worse on rotation and extension • Functional activities • Realistic expectations • Clinical reasoning of psycho-social factors • Absence of cough/sneeze/Valsalva symptoms <p>CLINICAL FINDINGS</p> <ul style="list-style-type: none"> • Active ROM extension, Ipsilateral sf, Ipsilateral rotation • Combined movements • Pain on local palpation • Absence of wide-spread hyper-algaesia and analodinia • No neural tensions signs • Psycho-social screening tool • Flexion not aggravating combined movement • Pain <ul style="list-style-type: none"> Quality (aching) On rising in morning Variable Non-neurologic | <p>Diagnosis group 3 Group agreed a list of signs and symptoms:</p> <p>Signs:</p> <ul style="list-style-type: none"> • Localised tenderness (para-spinal) • Localised tenderness over joint • No tenderness on sacroiliac joint palpation • No pain provocation on straight leg raise (to exclude neural tension) <p>Symptoms:</p> <ul style="list-style-type: none"> • Pain increases on standing for long periods • Pain increases when climbing stairs • Pain increases on extension • Pain increases on lateral rotation • Pain decreases when lying down • Pain decreases on flexion • Can have radiation to back and thigh + buttocks but not below knee • No pain radiating to groin • Absence of Radicular symptoms and signs • Time > 3 months • Had course of physiotherapy that has not resolved back pain <p>Based on the list of signs and symptoms the group generated a further list that was ranked:</p> <p>A. All signs listed plus all symptoms minus morning stiffness, time >3 months B. As A. time > 1 year C. As A. time > 6 months D. As A. time > 1 year and unsuccessful course of physiotherapy E. As A. time plus MRI F. As D. time PLUS MRI G. As A. plus diagnostic injection</p> <p>After an initial ranking a further ranking produced a top three options: Rank 1: (D), Rank 2 (A), Rank 3: (C).</p> | <p>Diagnosis group 4 Group generated list of 18 items and votes were cast on acceptability:</p> <p>A: Diagnostic injection (5 votes) B: Pain increase on extension (7 votes) C: Pain increase on twisting movement (3 votes) D: Pain increase on palpation (6 votes) E: Pain increase extension and rotation (7 votes) F: Pain increase lateral flexion – towards painful side (6 votes) G: No normal MRI/Radiological evidence H: Rising from flexion (7 votes) I: No red flags (inc Radicular symptoms) (7 votes) J: No Sacro Iliac joint pain (pain provocation test) (7 votes) K: Pain on standing (5 votes) L: Pain on walking (3 votes) M: Patients pain distribution para vertebral (6 votes) N: Age > 35 (4 votes) O: BMI > 40 (3 votes) P: + Decrease in pain in opposite movements (3 votes) Q: Extension and lateral flexion (7 votes) R: Pain increase walking up or down hill (4 votes)</p> <p>Four groups were generated starting with all items with the highest acceptability score (which was 7) these were then ranked.</p> <p>Rank 1: (Z) X + D + M Rank 2: (Y) X + D Rank 3: (W) X + P Rank 4: (X) B + E + H + I + J + Q</p> |
| <p>Plenary discussions and outcomes Results groups sessions were combined and presented for discussion The following option was discussed: Increased pain on extension Increased pain on rotation</p> | <p>Increased pain on rising from flexion Increased pain on extension/lateral flexion No radicular symptoms No SI joint pain Pain provocation test There was no final vote on this item on the day. Consensus was reached Post-conference; via email voting.</p> | <p>Participants were asked the vote on the following being 'acceptable'.</p> <ol style="list-style-type: none"> 1. Increased pain unilaterally or bilaterally, on lumbar para-spinal palpation AND 2. Increased low back pain on <u>one or more of</u> the following; extension (more than flexion), rotation, extension/side flexion, extension/rotation AND | <p>3. No radicular symptoms (defined as pain radiating below the knee) AND 4. No sacro-iliac joint pain elicited using a pain provocation test.</p> <p>Question issued to 45 physios/scope practitioners/psychologists. Responses received: 23. Acceptable; YES = 22, NO = 1</p> |

Table 3. Group and Plenary Results from Facet injection Study Consensus Conference looking at: What is the agreed technique for the injection of facet joints?

| | | | |
|---|---|--|---|
| <p>The 14 Injection topics open for discussion/agreement 1 Pre – injection consent/risk management 2 Processes used to select facet joints to be injected 3 Identification and visualisation of the selected joints 4 Positioning of the patient</p> | <p>5 Skin cleansing/sterilisation methods/ materials 6 Administration of local anaesthetic/ composition 7 Gauge/type/length of needle 8 Method to approach joint 9 Methods used to confirm intra-articular positioning of needle</p> | <p>10 Dose of radiation 11 Optimal type/configuration of X-ray machine/equipment etc. 12 Injectate volume 13 Injectate composition 14 After care advice</p> | <p>Groups voted on an item being 'acceptable' (i.e. not necessarily what they themselves would do or advise but an acceptable method/technique). Items with disagreements were discussed, alternatives suggested and voted/ on or ranked.</p> |
| <p>Group 1. Injection Technique There was consensus as per protocol for items: 1, 4, 5, 6, 7, 8 & 11</p> <p>Item 2 was discussed as two from the group found the protocol not acceptable. Following discussion, 3 Options ranked: Rank 1: (A) As protocol Rank 2: (B) As protocol but 8 joints not 6 as maximum Rank 3: (C) As protocol 'A' but one of the joints must be LS/S1</p> <p>Comments noted against item 2: Interval between injections 3 – 6 minutes?</p> <p>Two found items (3 & 9) not acceptable (there was no time for discussion on these)</p> <p>Item 10 was discussed as a number in the group found protocol not acceptable. Following discussion, 3 Options ranked: Rank 1(X): As protocol Rank 2(Z): Intermittent Fluoroscopy Rank 3 (Y): Upper limit of radiation that is agreed locally</p> <p>Item 11 was discussed as three in the group found protocol not acceptable. Following discussion, 4 Options ranked: Rank 1(D): As protocol but with 1ml Levo Bupivacaine Rank 2(C): As protocol using Levo Bupivacaine Rank 3(B): 1ml instead of 2ml (same drugs) Rank 4 (A): As protocol</p> <p>Comments noted against item 11: <ul style="list-style-type: none"> Levo Bupivacaine (less cardio toxicity) 2ml too high volume – 0.50 – 1ml </p> | <p>Group 2. Injection Technique There was consensus as per protocol for items: 3, 4, 5, 10, 11 & 14 – 9 after discussion</p> <p>Item 1; As a result of discussion: <ul style="list-style-type: none"> Concern -> variation in study centres risk management... could affect outcomes Define brief Clinical assessment Item 2; As a result of discussion: <ul style="list-style-type: none"> Up to 6 Single injection possible (i.e. remove statement 'we anticipate two injections...') <p>Item 6; as a result of discussion: <ul style="list-style-type: none"> Skin -> Weal Composition 1% lidocaine Via 25g needle into skin + subcutaneous tissues at needle entry point Rephrase; 1% lidocaine Via 25g needle into skin+ subcutaneous tissues at needle entry point <p>Item 7; As a result of discussion: <ul style="list-style-type: none"> 22gauge 10 -15 cm Quinke needle (depending on body Habitus) <p>Item 8; As a result of discussion: Guide to joint cleft if possible intracapsular if not.</p> <p>Item 12: As a result of discussion: 2ml per joint (some will be peri articular some intra articular)</p> <p>Item 13; As a result of discussion: <ul style="list-style-type: none"> Methylprednisolone, 20mg Bupivacaine, 7.5 mg </p> </p></p></p> | <p>Group 3. Injection Technique There was consensus as per protocol for items: 8, 10 & 11 after discussions items 1, 3, 5, 7 & 14 were agreed as protocol.</p> <p>Item 2 was discussed as two from the group found the protocol not acceptable. Following discussion, 2 Options ranked: Rank 1: (Y) As protocol + injection +/- Sacra... joint inject... if required Rank 2: (X) As protocol</p> <p>Item 4 was discussed as two from the group found the protocol not acceptable. Following discussion, 2 Options ranked: Rank 1: (F) As protocol + Prone position with pillows for lordosis. Rank 2: (E) As protocol</p> <p>Item 6 was discussed as three from the group found the protocol not acceptable. Following discussion, 3 Options ranked: Rank 1(Q): As protocol + Max 1ml per injection site. Rank 2(R): As protocol + Max 0.5ml per injection site. Rank 3 (P): As protocol</p> <p>Item 9 was discussed as two from the group found the protocol not acceptable. Following discussion, 4 Options ranked: Rank 1 (A): As protocol (parallax undefined). Rank 2 (D): As protocol but without parallax. Rank 3 (C): As protocol but parallax intermittent. Rank 4 (B): As protocol but parallax continuous</p> <p>Item 12 was discussed as three from the group found the protocol not acceptable. Following discussion, 4 Options ranked: Rank1(P): 2ml (as protocol), Rank2(Q): 1.5ml, Rank3(R): 1ml, Rank4(S): 0.5ml</p> <p>Item 13 was discussed as four from the group found the protocol not acceptable. Following discussion, 2 Options ranked: Local anaesthetic: 2 options were ranked: Rank 1 (A): L –Bupivacaine, Rank 2 (B): Bupivacaine. Steroid: 2 options were ranked: Rank 1 (X): Triamcinolone, Rank 2 (Y): Depo-Medrone (as protocol).</p> <p>Sub question (Item 13): 2 options were ranked: Rank 1 (U): As protocol with exclusion of systemic steroid use in last 3 months. Rank 2 (T): As protocol</p> | <p>Group 4. Injection Technique There was consensus as per protocol for items: 1, 3, 5, 6, 7, 8, 10 & 14. After discussions items 2, 11, 12 & 13 were agreed as protocol.</p> <p>Item 4 was discussed as one from the group found the protocol not acceptable. Following discussion, 2 Options ranked: Rank 1: (B) As protocol .plus measures to eliminate lumbar lordosis. Rank 2: (A) As protocol.</p> <p>Item 9 was discussed as two from the group found the protocol not acceptable. Following discussion, 2 Options ranked: Rank 1: (X) As protocol Rank 2: (Y) As protocol but needle does not have to be oblique</p> |
| <p>Plenary discussions and outcomes Results from the morning sessions were brought forward. Items: 1, 2, 3, 4, 5, 7, 8, 10, 11 & 14 were briefly discussed but there was general consensus on these.</p> <p>Item 6. was discussed 3 options were ranked: Rank 1(P): As protocol. Rank 2(Q): Max 1.0ml per injection site Rank 3 (R): Max 0.5ml per injection site</p> | <p>Notes: 44 Ballots two of which were spoiled (total included 42)</p> <p>Item 9. was discussed 3 Options were ranked: Rank 1 (A): As protocol. Rank 2 (C): As protocol adding intermittent Parallax. Rank 3 (D): No Parallax (remove from protocol). Notes: Adding continuous Parallax to protocol was discarded before ranking.</p> | <p>Item 12. 4 options ranked: Rank1 (P): 2ml per joint (as protocol). Rank2(R): 1ml. Rank3(Q): 1.5ml. Rank4(S): 0.5ml</p> <p>Notes: 41 Ballots, one noted not qualified to respond. 15 participants did not rank all four items just giving their top one or two.</p> <p>Item 13. Local anaesthetic. Two options voted on (Bupivacaine & lidocaine) both receive 6 votes.</p> | <p>Item 12 cont. Steroid 2 options were voted on: Triamcinolone (18 votes). Depo-Medrone (as protocol) (6 votes). Either (12 votes) Notes: There were 36 valid votes</p> <p>A number of results were confirmed post conference see below.</p> |

Table 4. Group and Plenary Results from Facet injection Study Consensus Conference looking at: What is the optimal conservative management/rehabilitation for patients with low back pain where facet joints have been identified as a contributing source of symptoms?



Best usual care package

Table 4. presents the results from the four morning sessions leading to the afternoon plenary session. The morning sessions discussed the acceptability of the proposed protocol items and additions, both cognitive and physical, were discussed and voted on. Comprehensive packages were proposed in all groups and these were taken forward to the afternoon plenary session. Whilst a result was reached some clarification was sought post-conference (see below).

Size of Signal

Table 5. below summaries the results of the discussions. Note, there was considerable discussion in these groups and some questions were not covered due to time constraints.

Table 5. Summary of results from the morning small group discussions related to: 'What is the difference in magnitude of response between treatment and control groups that should be considered large enough to establish the scientific or therapeutic importance of the results?'

Q 1.1. At 3-months, should we be seeking a mean between-group difference in change scores that is smaller / the same / or larger than that observed for the trials of manual therapy?

| | | Group 1 (total votes) | Group 2 (total votes) |
|----------|---------|-----------------------|-----------------------|
| A | Smaller | 1 | 0 |
| B | Larger | 6 | 9 |
| C | Same | 2 | 2 |

Q 1.1a. Additional question asked in group 1: Should we be asking the number that got better/difference in benefit?

| | | Group 1 (total votes) | |
|----------|---------|-----------------------|----|
| A | Smaller | 2 | NA |
| B | Larger | 4 | NA |
| C | Same | 3 | NA |

Q 1.2. Informed by the MID-units calculated for the trials of manual therapy (supporting evidence), at 3-months should we be seeking a small (<0.5), medium (0.5-1.0) or large (>1.0) MID-unit as proof of important difference?

| | | Group 1 (total votes) | Group 2 (total votes) |
|----------|----------------|-----------------------|-----------------------|
| A | Small (< 0.5) | 8 | 2 |
| B | Med (0.5-1.0) | 1 | 5 |
| C | Larger (> 1.0) | 0 | 1 |

Q 1.3. What magnitude of reduction in pain after the injection constitutes immediate pain relief? Group 1 discussions generated the four suggestions below. They then ranked them in order of preference.

| | | Group 1 (Ranking) |
|----------|-------|-------------------|
| A | 80% | 2 nd |
| B | > 50% | 4 th |
| C | 0% | 3 rd |
| D | 60% | 1 st |

Results from the morning sessions were brought forward to the afternoon plenary session where there was a considerable amount of discussion about this topic. As there was a difference of opinion

from the morning session for question 1.2 the whole group were asked to vote on the two items, A. Small (< 0.5) and B. Med (0.5-1.0). There were 48/49 valid votes with the outcome:

- Small (<0.5) – 8 votes
- Medium (0.5-1.0) – 40 votes

An additional question was posed: 'What difference in those who achieve minimally important change (MIC) is good? The group were asked to vote on three options: Larger, same and smaller. 44/49 ballots were valid with the result being:

- Larger – 22 votes
- Same – 9 votes
- Smaller – 13 votes

During discussion it was raised about the study measuring pain relief at one hour. A vote asking 'should we assess pain at one hour? The result was inconclusive with a total of 46 valid votes: 22 saying yes and 24 saying no.

Finally, the group revisited question 1.3. What magnitude of reduction in pain after the injection constitutes immediate pain relief? (see table 6 above). Four options were suggested (some extracted from the morning session) and 46/48 valid votes were included (see items/result below).

- 30% - 4 votes
- 50% - 22 votes
- 60% - 12 votes
- 80% - 8 votes

Sub Group Analysis

There was one group discussion on this topic. Participants were presented with current evidence and asked to consider the variables they felt were important. Lists were generated and items collapsed into categories. This resulted in a list of 10 variables. These were then ranked in order of importance.

Table 6. below summarises the result from this group.

| Table 6. Showing the final variables and order after ranking | | |
|--|----|---|
| Final rank | ID | Variables |
| 1 st | A | Severity |
| 2 nd | D | Anxiety/depression |
| 3 rd | M | Do you think you need an injection to get better |
| 4 th | E | Treatment expectations |
| 5 th | H | Back beliefs |
| 6 th | G | QOL |
| 7 th | B | Age |
| 8 th | F | Self-efficacy |
| =9 th | L | Forward flexion pain y/n |
| =9 th | N | Does the therapist think the treatment is effective |

The top five ranked items were presented to the plenary for information.

Post-conference:

Post- conference all voting and rankings from the day was checked and verified. A number of errors were noted in three of the design considerations (diagnosis, the process of facet joint injection and the best usual care package).

Diagnosis

In order to confirm the diagnostic criteria for the study 45 of the professional delegates were emailed to ask the following question:

We would like you to review the following text and confirm if the suggested clinical diagnostic criteria proposed for the study is 'acceptable'? Stating 'YES' or 'NO'.

Increased pain unilaterally or bilaterally, on lumbar para-spinal palpation. AND. Increased low back pain on one or more of the following; Extension (more than flexion), Rotation, extension/side flexion, extension/rotation. AND. No radicular symptoms (defined as pain radiating below the knee). AND. No sacro-iliac joint pain elicited using a pain provocation test.

Responses received: 23, Acceptable: YES = 22, NO = 1

The process of facet joint injection

Following the consensus conference there was uncertainty about the injectate to be used in the study. Six options were sent, via email, to 27 pain consultants/anaesthetists/professionals (delegates) who indicated they were responsible for injection. We received 11 responses; the results can be seen in Table 7 below.

Table 7. Results from email ballot of delegates to confirm injectate composition

| Injectate options | Preferred (enter X) = n | Acceptable (enter yes or no) = n |
|--|-----------------------------|-------------------------------------|
| Triamcinolone 10mg/ Levobupivacaine 2.5mg | 4 | Y = 5 N= 2 |
| Triamcinolone 10mg/ Levobupivacaine 5.0mg | 4 | Y = 5 N = 0 |
| Triamcinolone 10mg/ Levobupivacaine 7.5mg | 1 | Y = 6 N= 3 |
| Triamcinolone 20mg/ Levobupivacaine 3.75mg | 1 | Y = 3 N= 5 |
| Triamcinolone 20mg/ Levobupivacaine 7.5mg | 0 | Y = 4 N= 4 |
| Triamcinolone 20mg/ Levobupivacaine 11.25mg | 0 | Y = 2 N= 6 |

Best Usual care package

Confirmation of the number and duration of sessions was sought post-conference. We emailed 15 delegates who were physiotherapists, extended scope practitioners or clinical/health psychologists.

Two alternatives, a) and b) below, were sent and delegates were asked to state a preferred option and to also say if they felt it was acceptable or not.

There were 12 responses.

- a) 1 session of 60 minutes plus 5 sessions of 30 minutes (9 preferred, 7 yes, 0 no)
- b) Up to six sessions of 45 mins each (3 preferred, 6 yes, 1 no)

Among the 12 responses reported above, two responders answered both options were acceptable, one responder only provided a preference and did not state whether the options were acceptable and two responders preferred option a) and that this was the acceptable option.

Dissenting voices

Almost all delegates were very positive about the day. However, three delegates in total asked for their names to be removed from the Consensus group. Table 8. below gives the feedback we were given by these delegates

Table 8. Feedback from delegates who requested being removed from any publication resulting from the conference.

I took issue with several aspects of the consensus process, not least: the groups included lay members of public were asked to vote on highly technical decisions such as facet joint injection volume; and by the end of a long day, it felt like people (including clinicians) were being cajoled into voting for the sake of it whilst clearly not comprehending some of the decisions to do with statistics and study design. I felt that this whole process was exploiting evidence based medicine by trying to ensure not that the study would provide truth, but rather than it would garner wide agreement that there is indeed a legitimate role for facet joint injections, when the clinical evidence to date and the experience of several attending group members on the day make it clear that the benefit of injections is likely placebo. I do hope that the study adequately captures data on patient beliefs and expectations of both the treatment and clinicians, as was suggested in group sessions, because the placebo effect cannot be reliably detected by placebo control alone.
[Delegate 1]

Not agree on protocol

1. Different physio methods at different sessions as best usual care package in the study – needs standardising for study after assessment
2. Omit immediate assessment and 3 months too long for first assessment
3. PROM > RMDQ & NRS – not adequate or representative
4. 2 ml too much & 120mg Depo max dose too high
5. Standardise physio sessions

[Delegate 2]

I do not have a disagreement. I am unsure about statistics. Hence kindly exclude my name from publication

[Delegate 3]

Conclusions

We have established consensus from health professionals concerned with the treatment of facet joint pain in the UK on the assessment of facet joint pain, injection of facet joints, best usual care, minimal important difference and subgroup analysis for use in a feasibility study for a proposed clinical trial of facet joint injections. The process was evidence based and open to all those with a professional interest in this topic. It included lay participants and was undertaken in a transparent way. The use or not of facet joint injection is controversial internationally so consensus and transparency is essential for the design of the proposed trial of facet joint injections to ensure the results are acceptable to the whole pain treatment community.

Below we outline the areas where changes have been made to protocol as a result of the conference. A full protocol is available on the studies HTA webpages

http://www.nets.nihr.ac.uk/_data/assets/pdf_file/0019/130654/PRO-11-31-01.pdf

Diagnosis

Prior to the conference we had little or no clear protocol for the diagnosis of possible facet joint pain. The consensus has guided us towards a set of procedures that can be reproduced across practitioners, centres and is achievable in an NHS setting.

Table 9. Diagnostic criteria for study

- | |
|---|
| 1. Increased pain unilaterally or bilaterally, on lumbar para-spinal palpation |
| AND |
| 2. Increased low back pain on <u>one or more of</u> the following; |
| <input type="checkbox"/> extension (more than flexion) |
| <input type="checkbox"/> rotation |
| <input type="checkbox"/> extension/side flexion* |
| <input type="checkbox"/> extension/rotation* |
| AND |
| 3. No radicular symptoms (defined as pain radiating below the knee or objective neurological signs above the knee#) |
| AND |
| 4. No sacro-iliac joint pain elicited using a pain provocation test . |

*Both tests representative of regular compression patterns ([Edwards, 1999](#))

using a 'contracted' neurological examination ([McCarthy, 2010](#))

The process of injection

Below we outline the injection procedure. The consensus conference covered all areas of this and whilst a suggested protocol was produced as a starting point for discussion the current protocol was shaped by the conference. Key changes included the steroid being injected, how the radiological monitoring was managed and the volumes of all injectates.

The IMP will be 1ml of Levobupivacaine 5.0 mg/ml and 1ml of Triamcinolone 10mg/ml prepared within the same syringe will be used for each facet joint injection procedure. Preparation of the injection will be undertaken by the operator immediately prior to the injection. A total volume of 2ml will be injected through the spinal needle placed into each joint. Some facet joints may not be sufficiently large to take this volume of injectate meaning in practice that the injections will be intra- and peri-articular. This approach of mixing such drugs immediately prior to facet joint injection is standard practice for this procedure within the NHS.

When the participant attends for injection, the operator will make a brief clinical assessment to satisfy themselves that facet joint injections remain appropriate. Consent for the procedure will be obtained and the current pre-injection risk management procedures of the participating study centres will be adhered to. The operator will then inject the facet joint(s). Up to six facet joints in each individual (L3/L4, L4/L5; L5/S1) bilaterally.

Procedure to position the needle:

- No intravenous sedation required.
- Prone position with measures to reduce the lumbar lordosis, e.g. a pillow under the abdomen.
- Intravenous access, resuscitation equipment available.
- Skin cleansing with chlorhexidine 0.5% or 2% in alcohol, sterile drapes.
- X-ray imaging (C-arm fluoroscopy or other suitable equipment) to visualise joint. The dose of radiation used will be adequate to visualise the joint while minimizing X-ray exposure.
- Contrast medium will not be used.
- Local anaesthesia at needle entry point: 1% lidocaine via 25G hypodermic needle.
- 22G (0.7mm) needle with Quincke type point guided to joint cleft.
- Entry to the joint cleft may be indicated by X-ray appearance. Medial/lateral movement of the X-ray beam with intermittent screening to cause parallax shift may be used.
- If entry to the joint has not been achieved after repositioning the needle twice, the needle will be positioned on the joint line without further attempts at capsular puncture.
- Aspiration should be negative for blood or cerebrospinal fluid.
- The immediate post injection advice will be in accordance with the current procedures of the participating study centre.

Injection

- The operator will prepare the injection syringe to contain 1 ml of levobupivacaine 5.0mg and 1ml Triamcinolone 10mg in total volume; 2ml will be used for each joint.
- The full volume, 2ml, will be injected through the spinal needle placed into each joint. Some facet joints may not be sufficiently large to take this volume of injectate meaning in practice that the injections will be intra- and peri-articular. This reflects what we believe to be current practice in the UK.
- Resistance to injection may occur due to abutment of the needle bevel to a surface or due to filling of the intra-articular space:
 - Force should not be used.
 - The needle should first be rotated 90° and a further attempt at injection made.
 - If, after two further 90° rotations resistance to injection persists or if, after successful injection of a part volume resistance develops, gentle pressure should be maintained on the plunger and the needle withdrawn gradually until resistance to injection falls.
- After completion of the injection the needle is removed and a sterile dressing applied.

Best Usual Care Package (control Intervention)

Below we summarise the best usual care package. The consensus process has informed many aspects of this package. The package is, in simple terms, a toolkit of physical and psychological exercises/approaches which the therapist can use to provide a bespoke treatment programme to people with possible facet joint pain.

Session 1 – Assessment and planning (1 hour)

Patients initially undergo a thorough physical assessment based on the principles of Maitland manual therapy assessment and clinical reasoning². Symptomatic levels are identified and the severity and nature of the symptoms recorded and used to direct treatment.

Assessment includes discussion of expectations, fear avoidance and self-efficacy to assess any perceived challenges and barriers that patients feel may be preventing them from engaging in self-management of chronic pain and to allow subsequent treatment sessions to be tailored to individual need.

Session 2 to 6 (30 minutes each)

The aim of best usual care for this study is to provide a fully integrated psychological and physical rehabilitation. It is important therefore to integrate the two elements of care as far as possible so that participants do not see them as ‘stand-alone’.

Treatment should be directed at pain arising from the facet joint. Physiotherapists should use their full range of skills and knowledge in constructing a personalised rehabilitation programme using the comprehensive ‘tool kit’ provided. Certain elements of the ‘tool kit’ must be incorporated within the individualised programme and these must be recorded.

Table 10 below gives an overview of the different physical and psychological components of the package.

Table 10. An overview of components of the Best Usual Care package ‘toolkit’.

| Table 10. An overview of components of the Best Usual Care package ‘toolkit’. | |
|---|---|
| Modality/technique | |
| <input type="checkbox"/> Acceptance (Session 1) | |
| <input type="checkbox"/> Goal setting (Session 1 or 2) | |
| <input type="checkbox"/> Pacing (Session 1 or 2) | |
| <input type="checkbox"/> Challenging negative thoughts | |
| <input type="checkbox"/> Mindfulness | |
| <input type="checkbox"/> Manual therapy | |
| | <ul style="list-style-type: none">• Kaltenborn• McKenzie• Maitland• Cyriax |

| |
|---|
| <ul style="list-style-type: none"> • Osteopathic techniques • Mulligans • (NAGS/SNAGS/MWM) • Other |
| <input type="checkbox"/> Exercises (Session 1 or 2) |
| <ul style="list-style-type: none"> • Specific • Motor control retraining/core stability • Cardiovascular • Strength • Stretches • Other |
| <input type="checkbox"/> Soft tissue |
| <ul style="list-style-type: none"> • Myo-fascial • Trigger point • Soft tissue massage • Manipulation • Soft tissue release • Other |
| <input type="checkbox"/> Advice |
| <ul style="list-style-type: none"> • Pain terminology, mechanisms and pathways • Activities of Daily Living • Work and ergonomics • Lifestyle changes • Management of flare ups & changing symptoms • Paced home exercises • Other |

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Table 11. The Facet Joint Study Team

| The Facet Injection Study Team | | |
|--|---|---------------------------------------|
| Warwick Team | | |
| Professor Martin Underwood ^a | Dr Kirstie Haywood ^a | Ms Sophie Radford |
| Dr Hugh Antrobus ^a | Professor Charles Hutchinson ^a | Ms Marie Reynolds |
| Dr Shyam Balasubramanian ^a | Ms Amy Ismay | Azam Saied |
| Ms Kerry Barkan | Ms Suzanne Keohane | Dr Harbinder Sandhu ^a |
| Dr Alan Bennett | Dr Ranjit Lall | Professor Nigel Stallard ^a |
| Mrs Sally Brown ^a | Ms Claudia Lega | Mr Colin Tysall ^a |
| Dr Melinda Cairns ^a | Mr Tom Mars | Professor David Walsh ^a |
| Ms Sonia Davies | Mr Luke Parsons | Ms Christelle Kennedy |
| Dr David Ellard | Professor Stavros Petrou ^a | |
| Professor Frances Griffiths ^a | Dr Rachel Potter | |
| ^a Denotes co-applicants on the funding proposal | | |

Table 12. The Facet joint Consensus Delegates

| Consensus Delegates* | | |
|--|--------------------|-------------------------------|
| Olayinka Agbejule | Andrew Gunatilleke | Karen Le Marchand |
| Kanar Al-Quragooli | Julie Hall | Geoff Rose |
| Hugh Antrobus | Jing Lee | Sujaan Singh |
| Shyam Balasubramanian | Richard Makin | Eilish Simpson |
| Keith Bell | John O'Hanlon | Di Spalding |
| Alan Bennett | Shilpa Patel | Bhaskar Tandon |
| Stephen Bliss | Sarah Paterson | Madan Thirugnanam |
| Sally Brown | Helen Richmond | Justin Turner |
| Julian Campbell | Cheryl Ritchie | Colin Tysall |
| Helen Challinor | Nicholas Roberts | Bala Veemarajan |
| Robin Correa | David Rogers | Thirunavukkarasu Vishwanathan |
| Rob Froud | Audrey Rose | David Walsh |
| Janice Gastinger | Yadi Jayran-Nejad | Rebecca Warren |
| David George | Louise C Jeynes | Helen Welch |
| Aditi Ghei | Janet King | Lars Williams |
| Dorothy Goodwin | Zbigniew M Kirkor | |
| Jane Griffiths | Yvonne krantz | |
| *all reported delegates consented to inclusion | | |

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